

**REMARKS****I. Status of the Claims**

Claims 22-23 are pending herein. Claims 18-21 have been cancelled. Claims 22 and 23 have been amended to include the limitations of Claim 21. Furthermore, in order to overcome the Examiner's rejection of the claims under 35 USC 112, first paragraph, Applicant is attaching an executed Declaration from the inventor attesting to the fact that the sequence ID provided on 12/6/06 is inaccurate, and that the original SEQ ID and the SEQ ID dated 3/7/07 are identical and are the ones to be considered during the prosecution of this application. In addition, Applicant is providing the USPTO with Figs. 2, 3 and 4 which were referenced in the last response filed by Applicant, along with a copy of the Declaration from the inventor regarding these Figures. No new matter has been entered. In light of the foregoing amendments, attached declarations and the following remarks, Applicant respectfully requests the allowance of all pending claims.

**II. Claim rejections under 35 USC 112, first paragraph**

The Examiner rejected Claims 18-23 under 35 USC 112, first paragraph for lack of enablement. This ground of rejection, as it may apply to the pending claims, is respectfully traversed. Upon review of the record it is clear that the original sequence ID provided to the Office and the subsequent sequence ID provided to the Office on 3/7/07 are identical. However, the sequence ID provided to applicant by the Office dated 12/6/06 is inaccurate, and is responsible for the inconsistencies pointed out by the Examiner. Applicant herein attaches a declaration from the inventor attesting to the fact that the sequence ID provided on 12/6/06 is inaccurate, and that the original SEQ ID and the SEQ ID dated 3/7/07 are identical and are the only ones to be considered during the prosecution of this

application.

Applicant respectfully submits that the inconsistent SEQ ID's were responsible for this ground of rejection. Due to the fact that Applicant has attached a declaration clarifying the inconsistencies in the SEQ ID's provided to the Office, Applicant respectfully submits that this ground of rejection should now be withdrawn.

Moreover, the Examiner has rejected claim 22 under 35 USC 112 alleging lack of enablement for "a diagnostic agent for inflammatory diseases, "neoplastic diseases", dermatosis or "blood diseases of PMN macrophages and their lineages" which comprises an antibody of claim 18, in claim 22. This rejection of claim 22 under 35 USC 112 for lack of enablement, is respectfully traversed. The Examiner rejected Claim 22 under 35 USC 112, first paragraph for lack of enablement due to the fact that Figs. 2, 3 and 4 were missing. Applicant has attached the missing Figs 2, 3 and 4, which were referenced in Applicant's response to the previous Office Action, but were inadvertently not included with Applicant's response. Applicant respectfully submits that the submission of Figs. 2, 3 and 4 is sufficient grounds for the Examiner to withdraw the rejection of Claim 22 under 35 USC, first paragraph.

Moreover, Applicants refer the Examiner to the specification starting at page 24, line 25 to page 25, line 5, which recites:

"For example, an antigen specifically present in cancerous cells may be useful as a marker for tumor diagnosis. Also, antigens abundantly present in cell groups involved in inflammation, such as neutrophils, leak out into the blood as inflammation progresses, and thus their blood concentrations may be useful as markers for diagnosis of inflammation. Furthermore, antigens which are abnormally expressed in connection with skin diseases may be used as markers for those diseases.

Thus, assay systems for the above-mentioned calcium-

binding protein or fragments thereof may be used in diagnostic agents to yield useful information as an inflammatory disease marker, a neoplastic disease (especially epidermoid carcinoma of the skin, esophagus, respiratory tract, cervix, etc.) marker, a skin disease marker or a blood disease marker, for screening of patients during examinations, specifying the nature of diseases, monitoring the effects of treatment, etc. —"

Additionally, the specification starting at page 39, line 33 to page 40, line 18, discloses the expression of CAAF1, and page 40, line 9 recites:

"Also, the differences of cancer cells and normal cells in immunoreactivities against the anti-CAAF1 antibody suggest the usefulness of the anti-CAAF1 antibody as a diagnostic agent for cancer (particularly squamous-cell carcinoma of the skin, oral cavity, esophagus, respiratory organs and cervix). In addition, the immunoreactivity of neutrophils and macrophages against anti-CAAF1 antibody further suggests additional usefulness of the anti-CAAF1 antibody as a diagnostic agent for various inflammatory diseases —"

Based on the above, it should be clear that claim 22 does not suffer lack of enablement. A person skilled in the art would find claim 22 enabling in view of the specification alone even without the support of the accompanying declaration using experiments to substantiate enablement. Accordingly, it is respectfully requested that this rejection under 35 USC 112, first paragraph, be reconsidered and withdrawn.

### **III. Rejection of claims under 35 USC 102(b)**

The rejection of claims 18-19 and 22-23 under 35 USC 102(b) in view of Guignard et al., as it may apply to the pending claims, is respectfully traversed. Likewise the rejection of claims 18-20 and 22-23 under 35 USC 102(b) in view of Kelly et al. , as it may apply to the pending claims, is respectfully traversed.

Applicants have cancelled claims 18-21 and amended claims 22 and 23 to include the limitations of claim 21. Claim 21 was not anticipated by any of the references cited by the Examiner, and, thus, all pending claims, which include the limitations of claim 21, should now be in condition for allowance.

However, the following remarks address the Examiner's rejection of the claims in the event the Examiner may continue to reject the Claims as currently amended. Applicants submit there is no teaching in either reference of an antibody which is "specific to a calcium-binding protein comprising an amino acid sequence shown in SEQ ID. No. 19, or encoded by a nucleic acid sequence shown in SEQ ID NO: 1." Nowhere is there any teaching of a nucleic acid or amino acid sequence in either Guignard or Kelly nor has the Examiner made any allegation of teaching of the sequences. Both references just describe the antibodies and proteins, but nowhere is there any mention of the antibodies specific to the respective sequences. The Examiner uses Yamamura to help support the argument, and while it is not being relied on for the actual anticipation rejection, the reference itself is from 1996. Applicants point out that this application claims priority to its parent which issued as US 5,976,832 and was filed on December 6, 1995 which ultimately claims priority to JP 7-045564 and JP 7-070468 which were filed on March 6, 1995. Therefore, Applicants believe that Yamamura cannot be used as a reference under this section of the statute.

Moreover, SEQ ID No. 19 has been found both novel and nonobvious as evidenced by US Patent No. 5,976,832, which is the parent to this application and was involved in an interference No. 105,501, in which the Board of Appeals and Interferences has acknowledged SEQ 10 NO. 19 as being patentably distinct from SEQ ID NO: 20. Therefore, because the sequences underlying claims 22-23 are novel and nonobvious, Applicants submit that claims 22-23 of this application are also novel and nonobvious.

Accordingly, it is respectfully requested that these rejections under 35 USC 102(b) be reconsidered and withdrawn.

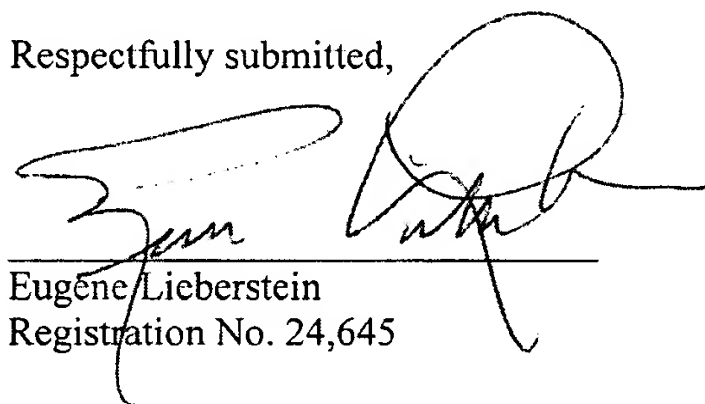
**IV. Rejection of claims under 35 USC 103(a)**

Claims 18-20 and 22-23 were rejected under 103(a) as being unpatentable over Dell'Angelica as combined with other secondary references. Applicant respectfully submits that pending Claims 22 and 23, which include the limitations of previous Claim 21, a claim that was not cited as being obvious in view of the cited references, should now be allowed. Accordingly, Applicant requests that the rejection under 103(a) be withdrawn and the Application be forwarded to issue.

**CONCLUSION**

In view of the foregoing amendments to the claims and remarks, it is respectfully submitted that the present invention as defined in claims 22-23 is in full compliance with all the statutory requirements of Title 35 USC, and, therefore, it is earnestly requested that the Examiner's rejections be withdrawn and that the pending claims be passed to issue.

Respectfully submitted,



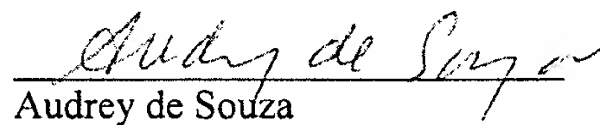
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**CERTIFICATE OF TRANSMISSION**

I hereby certify that this Amendment is being deposited via EFS-Web addressed to Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on December 4, 2008.



Audrey de Souza